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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,527	10/19/2001	Raymond A. Dwek	2543-1-023	1260

7590 07/15/2003

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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	14

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/042,527	DWEK ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10,11,14,15 and 39-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10,11,14,15 and 39-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 April 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This Non-Final Office Action is a response to the "Amendment and Response under 37 CFR 1.111" filed 14 April 2003 (Paper No. 12) in reply to the Non-Final Office Action mailed 5 November 2002 (Paper No. 10). Claims 1-4, 9-11, 14, 15, 25-28, 33-35 and 38 were considered in Paper No. 10. Claims 2-4, 9, 25-28, 33-35 and 38 were canceled, claims 1 and 14 were amended and claims 39-44 were added in Paper No. 12. Claims 1, 10, 11, 14, 15 and 39-44 are pending and under consideration.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Response to Amendment

Rejection of claims 2-4, 9, 25-28, 33-35 and 38 is rendered moot by cancellation of the claims in Paper no. 12.

Drawings

The formal drawings filed 22 April 2003 are approved by the draftsman.

Claim Rejections - 35 USC § 112

Rejection of claims 1, 10, 11, 14 and 15 under 35 U.S.C. 112, first paragraph, as lacking adequate written description is withdrawn in view of the amendment of claim 1 such that it is now limited to administering NB-DNJ.

Claims 1, 10, 11, 14, 15 and 39-44 are rejected under 35 U.S.C. 112, first paragraph, as lacking an enablement for the full scope of the claimed subject matter for reasons of record in Paper No. 10 and herein below under "New Grounds".

Double Patenting

Claims 1, 10, 11, 14, 15, 39 and 41-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 8 of copending Application No. 10/054,802 for reasons set forth herein below under "New Grounds Necessitated by Amendment".

Claim Rejections - 35 USC § 102

Rejection of claims 1, 10, 11, 14 and 15 under 35 U.S.C.§102(b) as being anticipated by any one of Platt *et al.* (1998; IDS AF), Platt and Butters (1998; IDS AO) or Aerts *et al.* (1998; IDS AH) is withdrawn in view of the amendment of the claims such that they are limited to administering NB-DNJ in combination with an enzyme involved in glycolipid degradation and bone marrow transplantation. The cited art does not explicitly teach that NB-DNJ should be the inhibitor of choice and, as pointed out by applicant at pages 6 and 7 of Paper No. 12, both Platt *et al.* and Aerts *et al.* teach away from the use of NB-DNJ in combination with enzyme replacement therapy. The limitation would therefore not have been obvious to the ordinary skilled artisan at the time of filing based on the teachings of the cited art.

New Grounds Necessitated by Amendment

Drawings

The drawings are objected to for the reasons set forth on the attached PTO-948. The formal drawings submitted 14 April 2003 are printed on sheets that are not the same size as the sheets on which Figures 1 and 9, which were not previously objected to by the draftsman, are printed. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 10, 11, 14, 15, 39 and 41-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 8 of copending Application No. 10/054,802. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claims of the instant application are drawn to a method of treating Gaucher disease comprising administering an inhibitor of NB-DNJ and a enzyme involved in glycolipid degradation. The claims of 10/054,802 are directed to a method of treatment comprising administering to a patient a combination of both a N-alkyl derivative of deoxynojirimycin having from about two to about twenty carbon atoms in the alkyl chain and a glucocerebrosidase enzyme. Claim 8 limits the method to treatment of Gaucher disease. Although the claims of 10/054,802 are not explicitly limited to NB-DNJ, the specification teaches that NB-DNJ is the most preferred embodiment of the N-alkyl derivative of deoxynojirimycin (see paragraph [0013]). Therefore, the method of claims 1, 10, 11, 14, 15, 39 and 41-44 would be obvious to one of ordinary skill in the art in possession of copending application 10/054,802.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

New Grounds

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 10, 11, 14, 15 and 39-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reducing GSL in the peripheral tissues comprising administering NB-DNJ in combination with an enzyme protein involved in glycolipid degradation or bone marrow transplantation, does not reasonably provide enablement

for a method of treating a glycolipid storage-related disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are limited to a method of treating a glycolipid storage-related disorder selected from Gaucher disease, Sandhoff's disease, Fabry's disease and Tay-Sach's disease. At paragraph 30, the specification defines "treatment" as "administration of medicine or the performance of medical procedures with respect to a patient, for either prophylaxis (prevention) or to cure the infirmity or malady in the instance where the patient is afflicted." According to this definition, the claims are directed to a method of preventing or curing Gaucher disease, Sandhoff's disease, Fabry's disease and Tay-Sach's disease. Therefore, given their broadest reasonable interpretation, the claimed subject matter encompasses prevention or complete remission of all symptoms of the indicated diseases and the correction of the underlying genetic defect. Although the previous office action indicated that the claims were enabled for a method of treating Gaucher disease, this assessment was based on the standard definition of the term "treatment" which is simply the medical management of a patient (see Stedman's Medical Dictionary) and does not require preventing or curing the disease.

For reasons set forth in Paper No. 10, the art teaches that curing GSL storage diseases which have a neurological phenotype is highly unpredictable. Further, although the findings of Example 3, shows that the survival of Sandhoff mice could be extended by coadministration of NB-DNJ and bone marrow transplantation, the mice were by no means cured of the disease. With regard to preventing or curing Gaucher disease, prevention or cure would require correction of the underlying genetic defect as anything less would merely provide symptomatic relief. As

correcting the genetic defect would require the successful application of gene therapy techniques, the claims are not fully enabled for the reasons set forth in the previous office action directed to the lack of enablement for a gene therapy approach.

Further, although the claims explicitly directed to gene therapy have been canceled and claim 1 is limited to administering an enzyme involved in glycolipid degradation, the claims still encompass administering an enzyme via gene transfer and therefore gene therapy. Thus, even claims limited to reducing GSL in peripheral tissues would lack enablement for the full scope of the claimed subject matter because the claims would still encompass a gene therapy approach.

Response to Arguments

In response to the arguments of record, Applicant states, "[o]ne of skill in the art would also appreciate that patients with other glycolipid storage-related disorders typified by systemic storage defects may also be treated by the methods of the invention" (page 4) and "[t]he methods of the present invention may, therefore, be used to advantage to alleviate adverse symptoms associated with systemic glycolipid deposition" (page 5). These arguments have been fully considered but are not found persuasive because Applicant has defined "treatment" as a method of preventing or curing a disease. Even if, as Applicant asserts, the present invention may be used to advantage to alleviate adverse symptoms associated with systemic glycolipid deposition, the claims are not limited to alleviating adverse symptoms but to preventing or curing various GSL storage-related disorders. For the reasons set forth in Paper No. 10 and herein above, the skilled artisan would not be able to prevent or cure any of the conditions named in the claims

without first engaging in undue experimentation. Thus, for reasons of record, the claims lack enablement for the full scope of the claimed subject matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
July 10, 2003

JAMES KETTER
PRIMARY EXAMINER